IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
ERIE DIVISION

TINA CARPENTER AND ALBERT CARPENTER, JR., Wife and Husband,	)	
Plaintiffs,	)	**Case No.** 13-77 Erie
v.	)	
	)	**COMPLAINT**
DIMA S.L., NEOMEDIC INTERNATIONAL, S.L., NEOMEDIC, INC., AND SPECIALTIES REMEEX INTERNATIONAL S.L.,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COME NOW Plaintiffs, by and through their attorneys of record, and for their causes of action against Defendants DIMA S.L., Neomedic International, S.L., Neomedic, Inc. and Specialties Remeex International S.L. allege and aver as follows:

GENERAL ALLEGATIONS
PARTIES

1. Plaintiffs Tina Carpenter (hereinafter individually referred to as "Plaintiff") and Albert Carpenter, Jr. are residents of the State of Pennsylvania.

2. Defendant DIMA ("DIMA") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at Poligono Industrial Mediavega Parcela 2.9, Calatayud, Zaragoza, Kingdom of Spain 50300.

DIMA's registered United States Food and Drug Administration ("FDA") Agent is Jeffrey R. Shideman, residing at 7307 Gouchester Dr., Edina, Minnesota 55435.

3. DIMA's FDA registration lists its proprietary device as "Needleless Sling."

4. Defendant Neomedic International, S.L. ("Neomedic International") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at C/Maestrat, 41-43 Terrassa, Barcelona, Spain 08225. Neomedic International is registered with the FDA as a foreign exporter and specification developer of the "Needless Sling."

5. Defendant Neomedic Inc. ("Neomedic") is a corporation organized and existing under the laws of Florida, with its principal place of business at 2655 Le Jeune Road, #810, Coral Gables, Florida, 33134. Defendant Neomedic Inc. is the United States headquarters of Neomedic International, S.L.

6. Defendant Specialties Remeex International, S.L. ("SRI") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at C/Tren De Baix, 55 Baixos Terrassa, Barcelona, Kingdom of Spain 08223. SRI's registered United States Food and Drug Administration ("FDA") Agent is Jeffrey R. Shideman, residing at 7307 Gouchester Dr., Edina, Minnesota 55435. Defendant SRI is registered with the FDA as the owner/operator of Neomedic International.

VENUE AND JURISDICTION

7. This Court has subject matter jurisdiction over this action and each of the plaintiffs' claims for relief pursuant to the provisions of 28 U.S.C. § 1332(a) because plaintiffs are citizens of the State of Pennsylvania, Defendant Neomedic is a citizen of the state of Florida and Defendants DIMA, SRI, and Neomedic International are citizens of a foreign state and the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

8. This Court has personal jurisdiction over this action and each of the plaintiffs' claims for relief because Defendants have sufficient contacts with the Western District of Pennsylvania such that they are subject to personal jurisdiction within said district in that they purposefully availed themselves of the privilege of conducting activities in this forum by placing their goods into the stream of commerce in the United States and this state in particular.

9. A substantial part of the events and omissions giving rise to plaintiff's claims arose and/or occurred in the Western District of Pennsylvania because plaintiff Tina Carpenter was implanted with Defendants' product in this jurisdiction and injured by Defendants' product in this jurisdiction.

10. Pursuant to 28 U.S.C. 1391(a), venue is proper in the Western District of Pennsylvania.

FACTUAL ALLEGATIONS

11. This is an action to recover damages for personal injuries suffered by Plaintiff who has been treated with the prescription medical device Contasure Needleless Sling ("Product"), as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, and/or sold or otherwise placed in the stream of interstate commerce of the United States, including this state, by Defendants.

12. The injuries suffered by Plaintiffs were caused by the wrongful acts, omissions, and fraudulent representations of Defendants.

13. At all times material hereto, the Contasure Needleless Sling was designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold by Defendants, for use by individuals including Plaintiff.

14. At all times herein mentioned the officers and directors of Defendants participated in, authorized and directed the production and promotion of the Product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the Product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiffs.

15. The Product was promoted by Defendants as safe and effective treatment for female urinary incontinence that could be installed by urologists in their patients

quickly and on an outpatient basis. Plaintiff and/or her physicians relied on Defendants' promises of safety. What Plaintiff received, however, were not safe devices, but devices known by Defendants to cause serious internal injuries.

16. Plaintiff Tina Carpenter was implanted with the Product on March 16, 2010 by Dr. Jennifer Stull at St. Vincent Health System in Erie, Pennsylvania, which was designed, manufactured, packaged, labeled, distributed and/or sold by Defendants. The Product was intended to treat Plaintiff for stress urinary incontinence, the use for which Defendants marketed the product. Plaintiff's treating physician implanted the Product properly and appropriately.

17. After, and as a result of the implantation of the Product, Plaintiff has suffered and will continue in the future to suffer severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic losses. Plaintiff has endured impaired physical relations with her husband, Albert Carpenter, Jr.

18. At all times material hereto, Defendants failed to comply or properly comply with United States federal law in connection with the Product.

19. The risk of serious injuries was known or should have been known to Defendants, but in spite of these risks, Defendants continued to market the Product to physicians and patients without adequate warnings.

20. Had Defendants properly disclosed the risks associated with the Product, Plaintiff would not have used it.

21. As alleged herein, as a direct and proximate result of Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the Product, Plaintiff suffered and will continue to suffer severe and permanent physical injuries. Plaintiff continues to endure substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

COUNT I

Negligence

22. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

23. Defendants, at all relevant times, had a duty to exercise reasonable care in the design, manufacture, labeling, testing, distributing, advertising, marketing, promoting, warning and/or sale of the Product into the stream of commerce, including a duty to ensure that the Product did not cause users to suffer from reasonably foreseeable, dangerous side effects and serious health problems.

24. Defendants at all relevant times knew or, in the exercise of reasonable care, should have known that the Product was of such a nature that it was not properly

designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and/or sold with the proper warnings, and was unreasonably likely to injure the Product's users.

25. Defendants so negligently and carelessly designed, manufactured, labeled, tested, examined, distributed, advertised, marketed, promoted, sold and/or supplied the Product, that it was dangerous and unsafe for the uses and purposes for which it was intended.

26. Defendants were aware or should have been aware of the probable consequences of the Product's use.

27. Defendants knew or should have known the Product would cause serious injury; however, they failed to disclose the known or knowable risks associated with the Product.

28. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, they acted in conscious disregard of the safety of the Plaintiff.

29. Defendants owed a duty to Plaintiff to adequately warn her and her treating physicians, of the risks associated with the Product and the resulting harm and risk it would cause patients.

30. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Product.

31. As a direct and proximate result of Defendants' breach, the Product used to treat Plaintiff's female urinary incontinence failed, resulting in the Plaintiff suffering serious injury, pain and harm.

32. As result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

33. Defendants' conduct in continuing to market, sell and distribute the Product after obtaining knowledge that it was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional punitive damages in such a sum as would serve to punish Defendant and to deter others from similar conduct in the future.

WHEREFORE, Plaintiffs pray for judgment in Count I against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT II

Strict Liability – Defective Design

34. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

35. At all times relevant herein, Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Product.

36. The Product is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purposes and/or its foreseeable risks exceed the benefits associated with its design.

37. At all times relevant herein, the Product was expected to reach, and in fact did reach, consumers in the State of Pennsylvania and throughout the United States without substantial change in the condition in which it was sold.

38. At all times relevant herein, Defendants intended for their Product to be surgically implanted into members of the general public, including Plaintiff, and knew or should have known that the Product would be surgically implanted into members of the general public, including Plaintiff.

39. The implantation of the Product into Plaintiff was reasonably foreseeable and it was used in the manner for which it was intended by the Defendants.

40. At all times relevant herein, the Product was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Product contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting individuals, including Plaintiff to risks that exceeded the benefit of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product, and/or the need for additional surgery as well as other severe and permanent health consequences;

b. When placed in the stream of commerce, the Product was defective in design, making the use of the Product more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with alternatives;

c. The Product's design defects existed before it left the control of Defendants;

d. The Product was insufficiently tested;

e. The Product caused harmful side effects that outweighed any potential utility; and

f. The Product was not accompanied by adequate instruction and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of

the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

41. In addition, at the time the Product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Product's utility.

42. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count I against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such

conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT III

Strict Product Liability – Manufacturing Defect

43. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

44. At all times relevant herein, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Product.

45. At all times relevant herein, the Product was expected to reach, and did reach, consumers in the State of Pennsylvania and throughout the United States without substantial change in the condition in which it was sold.

46. The implantation of the Product into Plaintiff was reasonably foreseeable and it was used in the manner for which it was intended by the Defendants.

47. At all times relevant herein, the Product was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Product contained manufacturing defects which rendered the Product unreasonably dangerous and subjected Plaintiff to risks that exceeded the benefit of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product, and/or the need for additional surgery as well as other severe and permanent health consequences;

b. The Product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The Product was not made in accordance with Defendants' specifications or performance standards; and

d. The Product's manufacturing defects existed before it left the control of Defendants.

48. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will

continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count III against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT IV

Strict Product Liability – Failure to Warn

49. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

50. The Product was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the Product including but not limited to its propensity to cause injury, subjecting Plaintiff to risks that exceed the benefit of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product and/or the need for additional surgery as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for female urinary incontinence.

51. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Product.

52. At all times relevant herein, Defendants intended for the Product to be surgically implanted into members of the general public, including Plaintiff, and knew or should have known that the Product would be surgically implanted into members of the general public, including Plaintiff.

53. Placement of the Product into Plaintiff was reasonably foreseeable and it was used in the manner for which they were intended by Defendants.

54. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

55. Defendants, as manufacturers, designers, distributors, and/or sellers of the Product are held to the level of knowledge of experts in the field.

56. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants.

57. The warnings that were given by Defendants were not accurate, clear and/or were ambiguous.

58. The warnings that were given by Defendants failed to properly warn physicians of the increased risks associated with the Product, subjecting Plaintiff to risks

that exceeded the benefit of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product and/or the need for additional surgery as well as other severe and permanent health consequences.

59. Defendants had a duty to warn Plaintiff of the dangers associated with the Product.

60. Had Plaintiff received adequate warnings regarding the risks of the Product, she would not have used it.

61. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count IV against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such

conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT V

Breach of Implied Warranties

62. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

63. Defendants designed, manufactured, marketed, distributed, supplied and sold the Product for the treatment of female urinary incontinence.

64. Defendants sold the Product which was implanted into Plaintiff, and prior to its implantation, Defendants impliedly warranted to Plaintiff, and to her physicians and health care providers, that the Product was of merchantable quality and safe and fit for the uses for which it was intended.

65. Plaintiff and her physicians and health care provider reasonably relied on Defendants' judgment, statements and indications that the Product was fit for such uses.

66. At the time of the sale of the Product, Defendants knew, or should have known, that the Product's intended uses were to be surgically implanted into the body for the treatment of female urinary incontinence.

67. At the time of Plaintiff's receipt and/or use of the Product, the Product was being used for the purposes and in a manner normally intended, namely for the treatment of female urinary incontinence.

68. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the Product until after it was implanted in Plaintiff.

69. When the Product was distributed into the stream of commerce and sold by Defendants, it was unsafe for its intended uses, and not of merchantable quality, as warranted by Defendants in that it had very dangerous propensities when used as intended and implanted into a patient's body where it could cause serious injury, harm or death to the end user.

70. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count V against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such

conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT VI

Breach of Express Warranties

71. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

72. Defendants expressly warranted and/or represented to physicians and healthcare providers that the Product was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended uses.

73. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendants for use of the Product.

74. Plaintiff did so rely on the express warranties of Defendants herein.

75. The Product does not conform to the express representations because the Product is not safe and has numerous serious risks and side effects.

76. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Product was not safe and fit for the uses intended, and, in fact, produced serious injuries to the users.

77. As a result of the foregoing acts and/or omissions, Plaintiff was and still is caused to suffer and/or at a great risk of suffering serious and dangerous side effects including but not limited to serious infection, the need for additional procedures to remove and replace the Product and/or the need for surgery as well as other severe and permanent health consequences.

78. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count VI against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT VII

Fraudulent Misrepresentation

79. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

80. Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff and the general public, that the Product had been tested and was found to be safe and/or effective for the treatment of female urinary incontinence.

81. The representations made by Defendants were, in fact, false.

82. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

83. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare communities, to recommend, prescribe, dispense and/or purchase the Product for the treatment of female urinary incontinence, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the general public.

84. At the time the aforesaid representations were made by Defendants and, at the time Plaintiff was treated with the Product, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

85. In reliance upon said representation, Plaintiff was induced to and did use the Product, thereby sustaining severe and permanent personal injuries, including but not limited to serious infection, the need for additional procedures to remove the Product, as well as other severe and permanent health consequences.

86. Defendants knew and were aware or should have been aware that the Product had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

87. Defendants knew or should have known that the Product had the potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

88. Defendants brought the Product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

89. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count VII against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT VIII

Negligent Misrepresentation

90. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

91. Defendants had a duty to represent to the medical and healthcare community, and to Plaintiff, and the general public that the Product had been tested and found to be safe and effective for the treatment of female urinary incontinence.

92. The representations made by Defendants were, in fact, false.

93. Defendants failed to exercise ordinary care in the representation of the Product, while involved in its manufacture, sale, testing, quality assurance, quality

control, and/or distribution of said Product into interstate commerce in that Defendants negligently misrepresented the Product's high risk of unreasonable, dangerous side effects including, but not limited to, the risk of developing serious infection and permanent scarring.

94. Defendants breached their duty in misrepresenting the Product's serious side effects to the medical and healthcare community, to the Plaintiff, and the public in general.

95. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count VIII against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT IX

Loss of Consortium

96. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

97. Plaintiff Albert Carpenter, Jr. is lawfully married to Plaintiff and, as such, is entitled to the services, society and companionship of his spouse.

98. As a direct and proximate result of the foregoing, Plaintiff Albert Carpenter, Jr. was, and has been, deprived of the comfort and enjoyment of the services, society and companionship of his spouse, Plaintiff, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Albert Carpenter, Jr.'s injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from all Defendants as alleged herein.

99. WHEREFORE, Plaintiffs pray for judgment in Count X against Defendant for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT X

Punitive Damages: Willful and Wanton Conduct

100. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

101. Plaintiffs are entitled to punitive damages because the Defendants' wrongful acts and/or omissions were willful and wanton conduct and in conscious and intentional disregard of and indifference to the rights and safety of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the Product and by failing to provide adequate instructions and training concerning its use.

102. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Product despite available information demonstrating that the Product subjected patients to severe and permanent personal injuries, including but not limited to serious infection, the need for additional procedures to remove the Product, as well as other severe and permanent health consequences.. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the Product or provided proper training and instruction to physicians regarding use of the Product.

103. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the Product.

104. Defendants were or should have been in possession of evidence demonstrating that the Product would likely cause and/or caused serious severe injury. Nevertheless, Defendants continued to market the Product by providing false and misleading information with regard to its safety and efficacy.

105. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Product, thus preventing health care professionals, including Plaintiff's surgeon, and consumers, including Plaintiff, from weighing the true risks against the benefits of using the Product.

106. Defendants failed to provide adequate training, instructions and warnings to surgeons, including Plaintiff's surgeon, which could have prevented failure of the Product causing serious harm and suffering to patients, including Plaintiff.

107. As a result of Defendants' conduct, Defendants are liable to Plaintiffs in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment in Count IX against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiffs hereby request a jury trial.

Respectfully submitted, this the 14th day of March 2013 by:

/s/ Rosemary Pinto, Esq.
Rosemary Pinto, Esq.
Laura A. Feldman, Esq.
Feldman & Pinto
1604 Locust Street, 2R
Philadelphia, PA 19103
Email: rpinto@feldmanpinto.com
lfeldman@feldmanpinto.com

Of Counsel:
Derek H. Potts
Patricia L. Campbell
The Potts Law Firm, LLP
908 Broadway, 3rd Floor
Kansas City, Missouri 64105
Telephone: 816-931-2230
Facsimile: 816-931-7030
Email: dpotts@potts-law.com
Email: pcampbell@potts-law.com